IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC. and SCR PHARMATOP,)
bert in advanta or,	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Plaintiffs,)
) C.A. No. 11-733-LPS
V)
) PUBLIC VERSION
PADDOCK LABORATORIES, INC., PERRIGO	.)
COMPANY, PADDOCK LABORATORIES, LLC,)
EXELA PHARMA SCIENCES, LLC, EXELA)
PHARMSCI, INC., and EXELA HOLDINGS,)
INC.,)
)
Defendants.)

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF STANDING OR ALTERNATIVELY, TO ORDER JOINDER OF BRISTOL-MYERS SQUIBB UNDER RULE 19

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<u>INTRODUCTION</u>

For at least the reasons discussed below, Plaintiffs' and BMS's opposition to Defendants' motion is incorrect. Defendants' motion should be granted because BMS retains substantial rights in the patents.

First, Plaintiffs assert that Pharmatop and Cadence have standing solely because Pharmatop is a patentee and Cadence is an exclusive licensee, and both retain rights in the patents. But Defendants have never claimed that Pharmatop and Cadence don't possess rights in the patents or that they should not be in the case – indeed, the presence of Pharmatop and Cadence is required in addition to that of BMS. Prudential standing requirements mandate that all parties who possess substantial rights associated with the patents must be present in order for Fourth, BMS suggests that there is no risk to Defendants of additional litigation because BMS is in privity with Plaintiffs and would be bound by the judgment in this case. However, the cases cited by BMS do not guarantee Defendants protection from multiple suits. More importantly, they are irrelevant because a licensor's agreement to be bound by judgments cannot circumvent the Supreme Court's mandate that it be joined in a patent infringement suit.

Finally, it is important for the Court to understand that this motion seeks to address two issues. In addition to requiring all parties with substantial rights in the patents to be in the case, Defendants also seek to keep Plaintiffs and BMS from obstructing discovery. BMS possesses documents in France that are relevant to the testimony of a BMS witness from France that Plaintiffs intend to present at trial. But BMS refuses to produce those documents because it claims they are subject to the same "French Blocking Statute" that this Court previously rejected in reference to Pharmatop. Plaintiffs and BMS will not be able to continue to evade discovery if BMS is a party to this case.

ARGUMENT

I. PLAINTIFFS' RIGHTS IN THE PATENTS ARE INSUFFICIENT TO PROCEED WITHOUT BMS

Plaintiffs' primary contention is that Pharmatop has sufficient rights to be in the case because it is an assignee of the patents, and Cadence has sufficient rights to be in the case because it holds an exclusive sublicense. (D.I. 247 at 6-9, 11-12.) Plaintiffs are able to make this argument because they confuse constitutional standing with prudential standing, and because they use literal language referring to the "patentee" from cases involving only two potential plaintiffs rather than three – when in fact the same principles from these cases apply to exclusive licensees like BMS. When the basic principles underlying these cases are properly considered,

however, it is clear that Plaintiffs do not possess sufficient rights in the patents to proceed without BMS.

A. "Constitutional Standing" Alone is Insufficient

There are two aspects to standing: "constitutional" requirements, and "prudential" requirements. See Intellectual Prop. Dev., Inc., v. TCI Cablevision of Cal., 248 F.3d 1333, 1345-48 (Fed. Cir. 2001). Constitutional standing refers to the fact that in order for a court to even consider a plaintiff's claim in the first instance, the plaintiff must allege injury fairly traceable to the defendants' conduct that will be redressed by the relief requested. Id. at 1346; Morrow v. Microsoft Corp., 499 F.3d 1332, 1338-39 (Fed. Cir. 2007). Prudential standing refers to additional "judicially self-imposed limits" on the exercise of jurisdiction. Intellectual Prop. Dev., 248 F.3d at 1348. Importantly, both constitutional and prudential requirements must be met in order for Plaintiffs to have standing. See Intellectual Prop. Dev., 248 F.3d at 1345-48; see also Morrow, 499 F.3d at 1338 (plaintiff "must meet both constitutional and prudential standing requirements"); Evident Corp. v. Church & Dwight Co., 399 F.3d 1310, 1313 (Fed. Cir. 2005) ("The doctrine of standing limits federal judicial power and has both constitutional and prudential components") (internal citation omitted).

The threshold constitutional aspect of standing derives from the Patent Act and is typically met when a party holds some portion of the exclusive rights to a patent. *Intellectual Prop. Dev.*, 248 F.3d at 1346-47. In this case, Defendants do not dispute that Pharmatop and Cadence each possess some portion of the exclusive rights associated with the patents in suit and have therefore met minimum constitutional standing requirements. Contrary to Plaintiffs' contentions, Defendants have never argued otherwise. Plaintiffs assert that because Pharmatop is

a "patent owner" that has not assigned all of its rights, "that is the end of the inquiry as to Pharmatop – and as to Defendants' arguments regarding constitutional standing." (D.I. 247 at 7.) Plaintiffs similarly assert that Cadence also has standing because it is an "exclusive licensee." (Id. at 9, 11.) These arguments relate solely to constitutional standing. They say nothing whatsoever about whether Plaintiffs also satisfy prudential standing requirements that they hold all substantial rights in the patents – which was the only basis for Defendants' motion to dismiss in the first instance. As noted below, they do not.¹

B. To Meet Prudential Standing Requirements, All of the Parties Holding Substantial Rights in the Patents Must be Present

The prudential standing requirement in patent cases is most-often seen in the well-established principle that an exclusive licensee having fewer than all substantial rights in a patent must sue jointly with the patent owner in order to have standing. *See Intellectual Prop. Dev.*, 248 F.3d at 1347-38 (citing cases). The primary basis for this requirement was articulated by the Supreme Court in *Independent Wireless Telephone Company v. Radio Corporation of America*, 269 U.S. 459 (1926), and has been reiterated many times by the Federal Circuit:

The presence of the owner of the patent as a party is indispensable not only to give jurisdiction under patent laws but also, in most cases, to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in the one action, or by satisfying one adverse decree to bar all subsequent actions.

Id. at 468 (emphasis added); see also Intellectual Prop. Dev., 248 F.3d at 1347.2 In other words,

¹ Contrary to Plaintiffs' contention (D.I. 247 at 14), defects in prudential standing cannot be "waived." *Mentor H/S. Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016, 1018 (Fed. Cir. 2001). The case relied upon by Plaintiffs concerned waiver of an argument pertaining to judicial review under the Administrative Procedure Act, which the court expressly characterized as "not jurisdictional." *Gilda Indus., Inc. v. United States*, 446 F.3d 1271, 1280 (Fed. Cir. 2006).

² Accord Schwarz Pharma, Inc. v. Paddock Labs., Inc., 504 F.3d 1371, 1374 (Fed. Cir. 2007); Evident, 399 F.3d at 1314; Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1131 (Fed. Cir. 1995). (cont. . . .)

the prudential requirement that the patent owner be joined when a would-be plaintiff holds less than all substantial rights exists to prevent the "possibility that the alleged infringer would be subject to multiple actions" if it were sued later by the patent owner who retained substantial rights in the patent and was not named in the case. *Schwarz Pharma*, 504 F.3d at 1374.

In addressing this requirement, the Federal Circuit frequently analyzes whether a party holds "all substantial rights" in the patent at issue. *See, e.g., Intellectual Prop. Dev.*, 248 F.3d at 1342-43; *Morrow*, 499 F.3d at 1339-40 & n.6.

These factors dovetail perfectly with the Supreme Court's statement of the primary rationale for prudential standing: to prevent a defendant from being subject to multiple lawsuits over the same patent. An absent party that retains the ability to enforce the patent retains sufficient rights in the patent and could bring another suit later unless it were joined in the lawsuit now. *See Schwarz Pharma*, 504 F.3d at 1374.

Typically, there are only two potential plaintiffs – a patent owner and an exclusive licensee – and the prudential standing analysis focuses on whether all of the substantial rights in the patent have been transferred from the assignee to the exclusive licensee such that the exclusive licensee can sue on its own. *See, e.g., Intellectual Prop. Dev.*, 284 F.3d at 1342-45

Another important concern "from the standpoint of the patentee, [is] ensuring that its patent is not invalidated or held unenforceable without its participation." *Evident*, 399 F.3d at 1314.

(analyzing transfer of rights from patent owner CPL to exclusive licensee IPD).⁴ In such a case, the courts analyze whether the patent owner has effectively transferred enough rights to the licensee to enable the licensee to become the "effective" or *de facto* owner of the patent. As explained by the Federal Circuit:

The all substantial rights inquiry is a proxy for the statutory requirement that a party bringing an infringement suit have the interests of a patentee, including the exclusionary rights granted by the patent statutes and other important incidental rights, such as the right to assign those rights or vindicate them through enforcement proceedings. See Sicom Sys., Ltd. v. Agilent Techs., 427 F.3d 971, 976 (Fed. Cir. 2005); Prima Tek II, L.L.C., v. A-Roo Co., 222 F.3d 1372, 1378-79 (Fed. Cir. 2000); Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 875 (Fed. Cir. 1991). The assignee becomes the "effective patentee."

Morrow, 499 F.3d at 1340 n.6. Notably, when there are only two parties, either the licensee has acquired all of the rights necessary to sue on its own, or it hasn't. If it hasn't, the patentee is said to have "retained" substantial rights and cannot therefore be absent from the case. See, e.g., Abbott, 47 F.3d at 1132 ("Diamedix retained substantial interests under the '878 and '285 patents, and Abbott therefore does not have an independent right to sue for infringement as a "patentee" under the patent statute"); Alfred E Mann Found., 604 F.3d at 1361 ("Where the licensor retains a right to sue accused infringers, that right often precludes a finding that all substantial rights were transferred to the licensee").

Where there are more than two parties in the chain of title to the patent, the same prudential considerations apply in that the parties present must possess all of the "substantial rights" associated with the patent. Were it otherwise, an infringer could be subject to multiple lawsuits because it could later be sued by an absent party that had retained a "substantial right"

⁴ See also Abbott, 47 F.3d at 1131-32 (analyzing transfer of rights from patent owner Diamedix to exclusive licensee Abbott); Speedplay, 211 F. 3d at 1250-51 (analyzing transfer of rights from inventor to exclusive licensee Speedplay).

to enforce the patent. This principle holds true regardless of whether the patentee is already in the case. The Federal Circuit recognized as much in Aspex Eyewear, Inc., v. Miracle Optics, Inc., 434 F.3d 1336 (Fed. Cir. 2006). In Aspex, "Contour," the patentee, granted an exclusive license to "Chic," which later assigned all of its rights to Aspex, although it was not clear whether it had done so before or after the start of the litigation. See id. at 1338-39. When Contour and Aspex alone attempted to file suit against the defendants, the district court dismissed the case on the grounds that Contour had transferred all substantial rights to Chic, making Chic the "effective" patentee. Id. at 1339. Reviewing the Contour/Chic agreement, the court of appeals vacated the decision on the grounds that Contour had in fact retained substantial rights in the patent. See id. at 1341. The court of appeals then returned the case to the district court, noting that as an exclusive licensee Chic would be a necessary party if it had not transferred all of its rights to Aspex prior to the start of the litigation. See id. at 1344. In so doing, the court of appeals reasoned that "[f]or the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent, there must be joinder of any exclusive licensee." Id. (emphasis added) (citing Independent Wireless, 269 U.S. at 466). Thus, the Federal Circuit recognized that the same prudential considerations apply when there are multiple parties in the chain of title to a patent as when there are only two parties: each of the parties retaining substantial rights in the patent must be present in the litigation in order for plaintiffs to have standing. Further, the fact that the patentee was already in the case made no difference to the analysis.

This case is similar to *Aspex Eyewear* and consistent with all of the case law addressing "substantial rights." BMS as an exclusive licensee assigned rights to Cadence prior to the start of the litigation. Similar to the situation with Chic, if BMS did not transfer all of its rights to Cadence before the start of the litigation (and it unquestionably did not), as an exclusive licensee

BMS is essential to the case "for the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent[.]" *Aspex Eyewear*, 434 F.3d at 1344. It does not matter that this case involves three entities in the chain of title rather than two, or that the missing party is an exclusive licensee rather than a patentee.⁵

Plaintiffs' only response to this clear law is to stand on formality alone. Plaintiffs assert that as long as Pharmatop is the formal "assignee" of the patent, it has standing regardless of whether the named parties possess all substantial rights in the patent. (D.I. 247 at 6-8.) To that end, Plaintiffs contend (without analysis) that all of the cases applying prudential concerns are inapplicable because those cases analyzed "whether a licensee (like BMS) possessed sufficient rights to sue without joining the patent owner (here Pharmatop) – precisely the opposite of the scenario herein." (D.I. 247 at 8.)

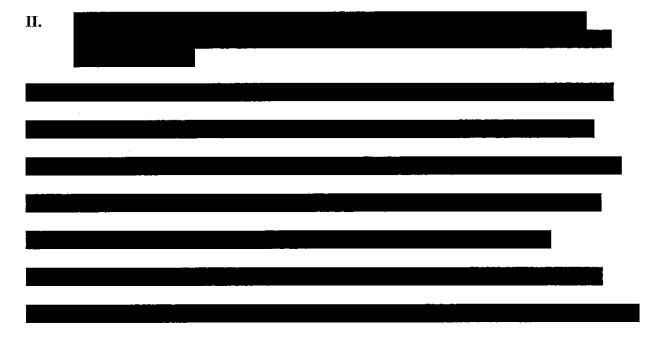
Plaintiffs are wrong. As already noted, *Aspex Eyewear* applies prudential concerns to the same situation here and was previously cited by Defendants. (D.I. 212 at 7.) Further, the first case relied upon by Plaintiffs to support their contention that this scenario is "the opposite" of previous case law proves them wrong: it actually determined whether a *licensor patent owner* possessed substantial rights by applying cases analyzing whether a *licensee* possessed substantial rights. *See Alfred E. Mann Found.*, 604 F.3d at 1357-59. In addition, Plaintiffs' contention that Pharmatop has standing solely because of its formal status as a patent owner is belied by the case law holding that if a formal title holder/patent owner transfers all substantial rights, its presence

⁵ The court noted that Chic would not have been a necessary party if it had transferred *all* of its rights to Aspex *before* the litigation started, *see id.* at 1344, in which case it would have simply been a "pass through" entity with no rights at all. Because there was no dispute that all of the rights had been transferred, the issue on remand concerned *when* the transfer occurred. *See id.* Here, there is no dispute about those issues: BMS transferred some rights to Cadence before the litigation but did not simply "pass through" all of its rights. *See infra* Section II; D.I. 212 at 3 – 5.

is *not* needed in the case. *Morrow*, 499 F.3d at 1340; *Intellectual Prop. Dev.*, 248 F.3d at 1345. Finally, it is well-settled that the title of an agreement transferring rights "is not determinative of the nature of the rights transferred under the agreement; actual consideration of the rights transferred is the linchpin of such a determination." *Intellectual Prop. Dev.*, 248 F.3d at 1344. Consequently, it does not matter for standing purposes whether Pharmatop is formally an assignee – what matters is the nature of the rights possessed by the relevant parties.⁶

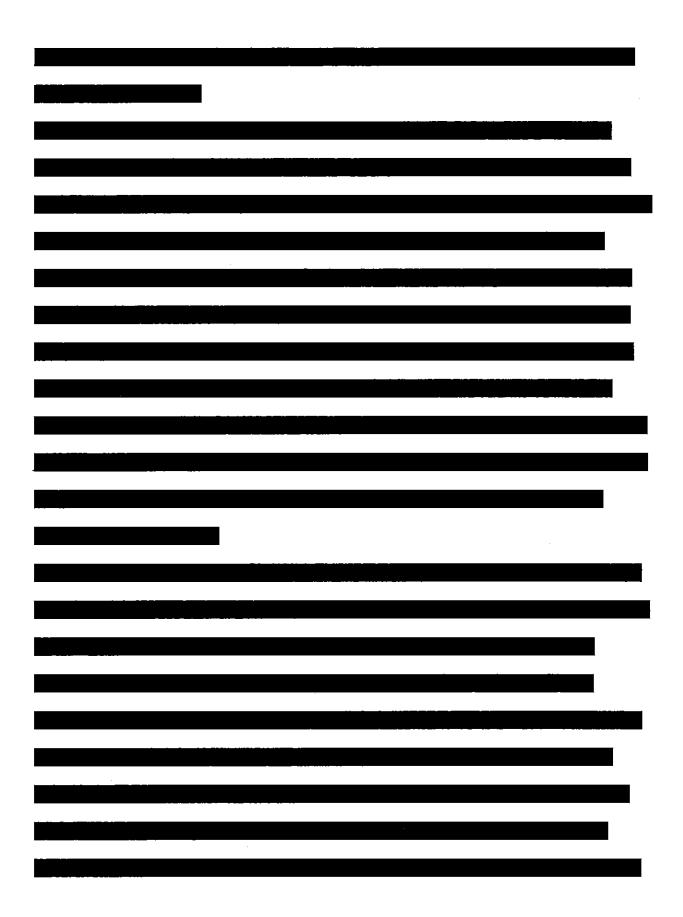
C. BMS Holds Substantial Rights in the Patents and is Not Present

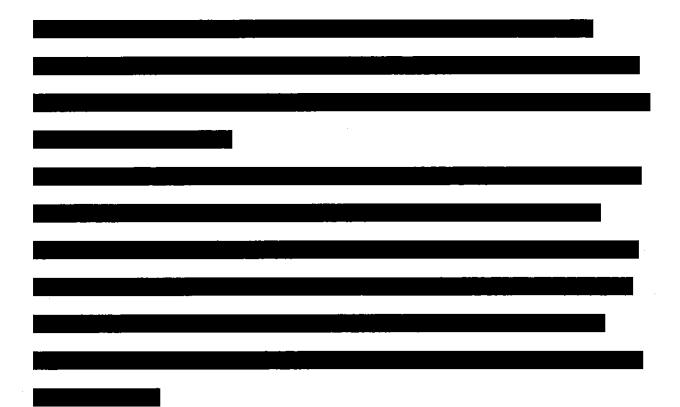
As discussed below, there is no serious question that although Pharmatop and Cadence have some rights in the patents, they do not possess all substantial rights – either individually or collectively. Those missing rights are held by BMS, which must be present for the case to proceed.



⁶ See also Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.p.A., 944 F.2d 870, 875 (Fed. Cir. 1991) ("It is well settled that 'whether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions."")(citing Waterman v. Mackenzie, 138 U.S. 252, 256 (1891).







IV. WHETHER BMS MAY BE IN PRIVITY IS IRRELEVANT TO STANDING

BMS asserts that Third Circuit law places BMS in privity with Pharmatop and that therefore BMS "cannot and will not seek to vindicate any rights" in the patents in the future.

(D.I. 246 at 3.) This does not relieve BMS of its responsibility to be in the case, for two reasons.

First, the cases relied upon by BMS do not support its assertion. In both *Amgen, Inc. v. Ariad Pharmaceuticals, Inc.*, and *Erbamount Inc. v. Cetus Corporation*, the court merely reasoned that there was a "strong possibility" (or a strong "probability") that the defendants could later successfully assert the doctrine of collateral estoppel against an absent patent-holder. *See Amgen*, 513 F. Supp. 2d 34, 44 (D. Del. 2007); *Erbamount*, 720 F. Supp. 387, 395 (D. Del.



1989). The court did *not* conclude the absent patent owners were in privity with the plaintiffs, and in fact concluded the absent parties *were* necessary parties. *See Amgen*, 513 F. Supp. 2d at 39-40, 44; *Erbamount*, 720 F. Supp. at 393, 395. Nor did the court in *Ortho Pharmaceutical Corporation v. Genetics Institute, Inc.*, conduct a privity analysis, and its "holding" cited by BMS is dictum because Ortho, as a nonexclusive licensee, had no standing to be in the case in the first place. *See* 52 F.3d 1026, 1033-34 (Fed. Cir. 1995).

Second, the law cited by BMS is inapposite because even an express agreement to be bound by the outcome of the case (which BMS has not provided) cannot "circumvent the rule of *Independent Wireless* that the patent owner must ordinarily join, in any infringement action, an exclusive licensee who possesses less than all substantial rights in the patent." *Prima-Tek II*, *L.L.C.*, *v. A-Roo Co.*, 222 F.3d 1372, 1381 (Fed. Cir. 2000). This prohibits the patentee or licensor from selectively "hunting" infringers without getting involved itself. *See id.* BMS's suggestion that it will not enforce its rights in the future is therefore irrelevant to the standing analysis.

V. PLAINTIFFS AND BMS CANNOT AVOID DISCOVERY

In addition to all of the foregoing reasons, BMS should be in the case because Plaintiffs and BMS are using its absence to deprive Defendants of necessary discovery. BMS claims that it has cooperated with a discovery subpoena served on it in New York by producing documents, but that is only half the story. Likely because of poor sales of Ofirmev (the alleged U.S. commercial embodiment of the patents), Plaintiffs have disclosed that they intend to rely upon the testimony of Jehan-Yves Drouin, an employee of BMS's French subsidiary, to discuss the commercial success of the embodiment of the patents outside of the United States (as well as other related secondary considerations). Yet, BMS has refused to produce documents it holds in France relevant to these issues on the grounds that they are subject to the same French Blocking

Statute that this Court previously rejected with respect to Pharmatop. (D.I. 104.) Although BMS asserts it has produced "23,000 pages of documents," it has not confirmed that it has produced *all* requested documents and it adamantly refuses to produce documents held by BMS France, which may be the most relevant to Plaintiffs' claims of commercial success in Europe. (Pardon Declaration, Ex. D.)¹⁰ Plaintiffs and BMS are effectively using BMS's absence from the case to shield potentially adverse information from discovery while at the same time seeking to benefit from Mr. Drouin's testimony. This provides an additional reason why BMS should be required to join the case.¹¹

CONCLUSION

For the reasons discussed above, the Court should dismiss the case for lack of standing or declare that BMS is a necessary party and order that it be joined.

¹⁰ Declaration of Edward J. Pardon in Support of Defendants' Reply Brief on Motion to Dismiss for Lack of Standing or, Alternatively, to Order Joinder of BMS Under Rule 19, filed herewith. Exhibits D and E are attached to this latter declaration.

¹¹ BMS also suggests that it is not subject to the personal jurisdiction of this Court. (D.I. 246 at n.1.) BMS is flatly wrong. BMS is a Delaware corporation with a registered agent in Delaware. (Ex. E.) It is therefore subject to jurisdiction in Delaware. See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 347 F. Supp. 2d 81, 83 (D. Del. 2004); see also Continental Cas. Co. v. American Home Assurance Co., 61 F. Supp. 2d 128, 129-30 (D. Del. 1999) (even a foreign corporation "which authorizes an agent to receive service of process in compliance with the requirements of a state registration statute has consented to the exercise of personal jurisdiction in that state").

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on November 7, 2012, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on November 7, 2012, the attached document was Electronically Mailed to the following person(s):

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